## REMARKS/ARGUMENTS

### I. Status of the Claims

Claims 1, 4-11 and 13-15 are pending in this Application. Claims 2-3, 12 and 16-39 have been canceled.

### II. 35 U.S.C. § 103 Rejection – *first paragraph*

**A. Claims 1, 4-11, and 13-15 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Stjernschantz et al. of WO 00/25771 A1.**

Claims 1, 4-11, and 13-15 have been rejected under 35 U.S.C. 103, first paragraph. The Office states that the present Application is unpatentable over Stjernschantz et al. of WO 00/25771 A1. According to the Office, Stjernschantz et al. teach of employing COX-2 inhibitors to treat inflammatory conditions of the eye. According to the Office, Stjernschantz et al. teach of treating glaucoma (the Office points to page 1, lines 1-4).

However, the Applicants respectfully point out that Stjernschantz et al. do not broadly teach the treatment of disorders of the eye with COX-2 inhibitors, but instead teach the treatment of iridial pigmentation which is "a local side-effect of prostaglandin treatment in the eye" (see page 1, lines 6-8). Stjernschantz et al. states that iridial pigmentation is a side-effect (page 3, lines 6-9) of prostaglandin treatment and has no harmful medical consequences but is instead, "a cosmetic disadvantage."

The Applicant's invention as defined by the amended claims, is for the treatment of blepharitis, post-operative inflammation and pain from corneal transplant surgery, endophthalmitis, episcleritis, keratitis, keratoconjuctivitis, keratoconjunctivitis sicca, post-operative inflammation and pain from lens implantation surgery, Mooren's ulcer and post-operative inflammation and pain from retinal detachment surgery. The Applicant's claims do not include treatments for glaucoma.

The Applicants respectfully point out that a case of prima facie obviousness has not been made. The Applicants point out that in order to establish a *prima facie* case of obviousness three basic criteria must be met.

> First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. (MPEP § 2142)

The Office must show all three of these elements to establish *prima facie* obviousness.

The first of these three factors is the suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.

This 103(a) rejection deals with a single reference.

The Applicants have reviewed Stjernschantz et al., but find that this Application concerns the use of COX-2 inhibitors for the treatment of iridial pigmentation, a side effect that is sometimes observed when prostaglandins are used for the treatment of glaucoma. The Applicants point out that Stjernschantz et al. have not disclosed the use of COX-2 inhibitors for various inflammatory disorders of the eye, and glaucoma is not included in the Applicant's claim set.

Therefore, because there is no suggestion of motivation to combine references, the first element of *prima facie* obviousness has not been satisfied.

Second, there must be a reasonable expectation of success. The Applicants point out that although COX-2 inhibitors are known anti-inflammatory inhibitors, there is no information provided in Stjernschantz et al. that would instruct an individual on the methods for using COX-2 inhibitors for the treatment of such disorders as blepharitis, post-operative inflammation and pain from

corneal transplant surgery, endophthalmitis, episcleritis, keratitis, keratoconjuctivitis, keratoconjunctivitis sicca, post-operative inflammation and pain from lens implantation surgery, Mooren's ulcer and post-operative inflammation and pain from retinal detachment surgery, which is the subject matter of the current claims. Further, Applicants are not aware that prostaglandin treatment is indicated for these claimed conditions. Therefore, there is no motivation to modify the Stjernschantz et al. reference for the use of a COX-2 inhibitor for the use of treating blepharitis, post-operative inflammation and pain from corneal transplant surgery, endophthalmitis, episcleritis, keratitis, keratoconjuctivitis, keratoconjunctivitis sicca, post-operative inflammation and pain from lens implantation surgery, Mooren's ulcer and post-operative inflammation and pain from retinal detachment surgery (see amended Claim 1).

Therefore, the second factor required for prima facie obviousness has also not been established.

The third criteria required to establish prima facie obviousness is that the prior art reference must teach or suggest all of the claim limitations.
The Application of Stjernschantz et al. does not disclose each of the claim limitations of the Applicants present Application.

First, the specific disorders are not disclosed anywhere in the Application. Although glaucoma is mentioned in the Stjernschantz et al. reference, glaucoma is not claimed in the present Application. The Applicants claim disorders such as blepharitis, post-operative inflammation and pain from corneal transplant surgery, endophthalmitis, episcleritis, keratitis, keratoconjuctivities, keratoconjunctivitis sicca, post-operative inflammation and pain from lens implantation surgery, Mooren's ulcer and post-operative inflammation and pain from retinal detachment, which are not disclosed by Stjernschantz et al.

Second, the instant Application claims numerous specific COX-2 inhibitors for the treatment of these disorders, but these COX-2 inhibitors have not been disclosed by Stjernschantz et al. These inhibitors include deracoxib, valdecoxib, parecoxib, a benzopyran COX-2 inhibitor, etoricoxib, 2-(3,5-difluorophenyl)-3-[4-(methylsulfonyl)-phenyl]-2-cyclopenten-1-one and 2-(3,4-difluorophenyl)-4-(3-

hydroxy-3-methylbutoxy)-5-[4-(methyl-sulfonyl)-phenyl]-3(2H)-pyridazinone, JTE-522, ABT-963, and L-776,967.

Thus, because the prior art reference does not teach or suggest all the claim limitations, the third element of *prima facie* obviousness has not been satisfied.

Because the Office has not established prima facie obviousness, the Applicants respectfully request that the rejection of Claims 1, 4-11 and 13-15 be withdrawn. The Applicants respectfully request the allowance of these Claims..

**III. Obviousness-type Double Patenting Rejection**

Claims 1, 4-11 and 13-15 have been provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 40 of copending Application No. 09/904,098. As acknowledged by the Office, the alleged conflicting claims have not been allowed. Applicants, therefore, will address the merits of the obviousness-type double patenting rejection when or if copending Application No. 09/904,098 is allowed.

**IV. Conclusion**

If the Examiner believes a telephonic interview with Applicant's representative would aid in the prosecution of this application, the Examiner is cordially invited to contact Applicant's representative at the below listed number.

Respectfully submitted,

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